MARYLAND
Department of Health
Institutional Review Board · 201 W. Preston St. · Baltimore, MD 21201
Carol Johnston, APRN, PMH, BC, Chair

The Maryland Department of Health (MDH) Institutional Review Board (IRB) is responsible for reviewing and approving all proposed research projects involving human subjects, covered by 45 Code of Federal Regulations (CFR) Part 46, occurring in any MDH facility. Projects involving data collection in which there is identifiable linkage to the subject or involving physical, social, psychological, or privacy risks to the subject require IRB review. The IRB is charged with the responsibility of determining if a project qualifies as being exempt from IRB review requirements.

Research involving any MDH unit or facility must be signed off by the Director or Administrator of the unit or facility prior to submitting to the IRB office. The Director's signature should appear on the line designated for the "MDH program administrator" on IRB form 1 (MDH 2124, Attachment 3). Any research involving Behavioral Health Administration (BHA) programs or facilities must be signed off by Dr. Barbara Bazron, Executive Director for BHA. Spring Grove Hospital Center and Clifton T. Perkins Hospital Center both have an independent research approval committee. Any proposal that involves research at these facilities must be approved by that facility's review board. See Attachment 1.

Any proposal that involves another collaborating institution or agency must be approved by all the collaborating institutions or agencies. Any research submitted by a student must be approved by the student's educational institution.

The IRB meets the third Thursday of each month. The deadline for proposals to be included for each meeting's agenda is 10 calendar days prior to the meeting date. Proposals will be reviewed in the order received. No more than five new proposals can be considered at any one meeting. See Attachment 2 for schedule. All proposals in excess of five or received after the cut- off date will be placed on the next month's agenda.

Proposals should include the following:

1. A completed form MDH 2124 (Attachment 3);

2. An abstract summary (For guideline, see Attachment 4);

3. Narrative including:

   a. Pertinent background information; and
   b. A detailed protocol

4. Copies of all instruments to be used, e.g., record abstraction form, interview form, questionnaire, etc.

5. Copies of all informed consents or disclosure statement when applicable (See Attachment 5 for elements of informed consent).

6. Assurance that an evaluation of ability to consent will be utilized if the proposed research involves cognitively impaired or mentally ill subjects.

7. Copies of IRB approvals from other involved institutions.

SEND AN ORIGINAL PROPOSAL AND TEN COPIES OF THE PROPOSAL TO:
(If your complete packet is more than 100 pages (double-sided) the copies should be on individual flash drives)

Institutional Review Board
201 W. Preston Street
Baltimore MD 21201

When your proposal has been scheduled for review, you will be informed of the date and approximate time of the review. Although it is not required that the principal investigator attend the IRB meeting, his or her doing so can facilitate the process should the Board members have questions regarding the protocol to be followed to carry out the proposal.

Should you have any questions as you prepare your proposal for submission, please feel free to contact Ms. Gay Hutchen, IRB Administrator. She can be reached at (410) 767-8448 or gay.hutchen@maryland.gov .

****PROTOCOLS SUBMITTED WITHOUT THE "MDH PROGRAM ADMINISTRATOR'S" SIGNATURE WILL NOT BE REVIEWED UNTIL THE SIGNATURE IS OBTAINED****

ATTACHMENT I

BEHAVIORAL HEALTH INSTITUTIONS WITH RESEARCH APPROVAL COMMITTEE

Spring Grove Hospital Center
Dr. Charles Richardson
(410) 402-6871

Clifton T. Perkins Hospital Center
Monica Chawla
(410) 724-3140

ATTACHMENT 2

IRB MEETING SCHEDULE FOR JANUARY 2018 - DECEMBER 2018

All proposals must be in this Office 10 days prior to the third Thursday of each month. Each proposal must have an original and 10 copies.

Proposal Due Dates	IRB Meeting Dates
January 8, 2018	January 18, 2018
February 5, 2018	February 15, 2018
March 5, 2018	March 15, 2018
April 9, 2018	April 19, 2018
May 7, 2018	May 17, 2018
June 11, 2018	June 21, 2018
July 9, 2018	July 19, 2018
August 6, 2018	August 16, 2018
September 10, 2018	September 20, 2018
October 8, 2018	October 18, 2018
November 5, 2018	November 15, 2018
December 10, 2018	December 20, 2018

ATTACHMENT 3

PROTOCOL #_____
IRB Office Use Only

MARYLAND DEPARTMENT OF HEALTH
OFFICE OF THE INSPECTOR GENERAL
INSTITUTIONAL REVIEW BOARD
FORM 1 (MDH 2124)

PROTOCOL STATUS: ____NEW APPLICATION
____ DISSERTATION/____STUDENT RESEARCH
____ RE-APPLICATION **(**new application resulting from approval lapse)

TITLE OF STUDY: _____
_____
_____

PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

CO-PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

STUDENT INVESTIGATOR: _____ _____
(Academic Advisor should be PI) **SIGNATURE** **PRINT OR TYPE NAME**

MAILING ADDRESS **(Include organizational affiliation, e.g. University or MDH Program):**_____
_____
_____

PHONE #_____ **FAX #**_____ **E-MAIL:** _____

FUNDING SOURCE: ☐ FEDERAL _____
(Provide the name of the agency ☐ STATE_____
on the line next to the source) ☐ OTHER _____

IF NO FUNDING SOURCE EXPLAIN HOW THIS STUDY WILL BE FINANCIALLY SUPPORTED:
_____
_____

PROVIDE THE NAME(S) OF THE MARYLAND DEPARTMENT OF HEALTH'S ADMINISTRATION(S) OR PROGRAM(S) PROVIDING DATA OR ALLOWING RECRUITMENT OF SUBJECTS FOR THIS STUDY:

1._____ 3._____

2._____ 4._____

HAVE YOU CONTACTED THIS/THESE MDH PROGRAM(S) REGARDING YOUR PROTOCOL?
☐ YES ☐ NO

HAVE THEY APPROVED YOUR PROTOCOL? ☐ YES ☐ NO (IF YES, SIGNATURE REQUIRED BELOW)

NAME OF MDH PROGRAM ADMINISTRATOR(S) AUTHORIZING INVOLVMENT IN THIS STUDY:
(Obtain signature(s) prior to submission to the IRB for review. *Protocols will not be reviewed without signature(s))

1._____ SIGNATURE_____
(PRINT) (DATE)

2._____ SIGNATURE_____
(PRINT) (DATE)

3._____ SIGNATURE_____
(PRINT) (DATE)

4._____ SIGNATURE_____
(PRINT) (DATE)

DOES THIS STUDY INVOLVE INTERACTION OR INTERVENTION WITH HUMAN SUBJECTS?
☐ YES ☐ NO

DOES THIS STUDY REQUIRE THE USE OF MDH DATA/DATA SET? ☐ YES ☐ NO

DOES THIS STUDY INVOLVE? (Provide details in protocol for any "yes" response)

MINORS (UNDER 18 YEARS OF AGE)	☐YES ☐NO	INTELLECTUAL DISABILITY	☐YES ☐NO
ELDERLY (≥65)	☐YES ☐NO	FETAL TISSUE OR ABORTUS	☐YES ☐NO
PRISONERS	☐YES ☐NO	RADIOACTIVE MATERIAL	☐ YES ☐ NO
DEVELOPMENTALLY DISABLED		INFECTIOUS AGENTS	☐ YES ☐ NO
INDIVIDUALS	☐YES ☐NO	PREGNANT WOMEN	☐ YES ☐ NO

DOES THIS STUDY POTENTIALLY INVOLVE? (Provide details in protocol for any "yes" response)

PHYSICAL RISK TO SUBJECT	☐YES ☐NO	SOCIAL RISK	☐YES ☐NO
PSYCHOLOGICAL RISK TO SUBJECT	☐YES ☐NO	PHYSICAL OR MENTAL DISCOMFORT TO SUBJECT	☐YES ☐NO
RISK OF DISCLOSURE OF INFORMATON POSSIBLY DAMAGING TO SUBJECT OR OTHERS	☐YES ☐ NO	INVASION OF PRIVACY	☐YES ☐NO

WILL INFORMED CONSENT BE OBTAINED? ☐YES ☐NO

ARE YOU REQUESTING A WAIVER OF INFORMED CONSENT? ☐YES ☐NO

IF YES, PROVIDE THE BASIS (IN ACCORDANCE WITH 45 CFR 46.116) FOR YOUR REQUEST: ____

_____

_____

ATTACHMENT 3

ARE YOU REQUESTING A WAIVER OF DOCUMENTATION OF INFORMED CONSENT (MUST MEET THE REQUIREMENT OF 45 CFR 46.117)? ☐ ES ☐ NO

ARE YOU REQUESTING A HIPAA WAIVER? ☐ YES ☐ NO IF YES, ☐ FULL ☐ PARTIAL

HAS THIS STUDY BEEN REVIEWED BY ANOTHER IRB? ☐ YES ☐ NO

IF YES, PLEASE PROVIDE COPIE OF IRB APPROVAL

IF NO, EXPLAIN WHY_____
_____
_____

ATTACH LIST OF ALL RESEARCH STAFF (INCLUDING PI) INDICATING DATE OF LAST ETHICAL/RESEARCH TRAINING

FOR THE IRB TO APPROVE A PROTOCOL, THE FOLLOWING CONDITIONS MUST BE MET. PLEASE ENURE THAT YOUR PROTOCOL ADDRESSES EACH OF THESE ITEMS.

- RISKS ARE MINIMIZED THROUGH SOUND RESEARCH DESIGN, NO UNNECESSARY EXPOSURE TO RISK, AND WHENEVER APPROPRIATE, USE DIAGNOSITIC OR TREATMENT PROCEDURES FAMILIAR TO SUBJECT
- RISKS ARE REASONABLY RELATIVE TO ANTICIPATED BENEFTS
- SELECTION OF SUBJECTS IS EQUITABLE
- INFORMED CONSENT IS OBTAINED (copy provided to participant)
- INFORMED CONSENT WILL BE DOCUMENTED (IF APPLICABLE)
- PROVISIONS TO PROTECT THE PRIVACY OF SUBJECTS AND CONFIDENTIALITY OF DATA ARE ADEQUATE
- ADEQUATE PROVISIONS FOR MONITORING DATA COLLECTION TO ENSURE SAFETY OF SUBJECTS
- APPROPRIATE SAFEGUARDS ARE INCLUDED FOR VULNERABLE SUBJECTS
- *ALL APPROPRIATE SIGNATURES

ATTACHMENT 4

GUIDELINES FOR PREPARING THE ABSRACT SUMMARY

An abstract summarizing each of the following items must be included with each application before it will be processed for Board review. The Abstract Summary must be single spaced and limited to no more than three pages. If an item is not applicable, please note accordingly.

AN ABSTRACT SUMMARY MUST ALSO BE PREPARED FOR RESEARCH SUBMITTED AS EXEMPT

1. Briefly summarize the purpose of this study including the methods and procedures to be used.

2. Describe the source for the study population and what is required of the subjects. (when the population consists of special groups such as prisoners, children and the mentally disabled or other groups whose ability to give voluntary informed consent may be in question, it is necessary to provide the rationale for using this particular population.)

3. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, a fetus or an abortus.

   If identifying information is to be collected from records, indicate the type of data to be retained, the purpose for which the data will be used, how long it will be retained in identifiable form, and how the disposition of the data will be handled.

4. Describe and assess any potential risks - physical, psychological, social, legal or other and assess the likelihood and seriousness of such risks.

   a. Describe procedures for protecting against or minimizing potential risks and assess their likely effectiveness.
   b. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

5. Assess the potential benefits to be gained by the individual subjects as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.

6. Describe consent procedures to be followed, including how and where informed consent will be obtained. When there are potential risks to the subject, or the privacy of the individual is involved, the investigator is required to obtain a signed informed consent statement from the subject. For subjects who are not able to give informed consent, signed informed consent must be obtained from the parent or authorized legal guardian of the subject. These subjects should be provided with information clearly stating what is to be expected in order that they may assent to participation. <u>Furnish an actual copy of the disclosure statement and/or the informed consent statement.</u>

   a. If signed informed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.
   b. If information is to be withheld from a subject, justify this course of action.

7. Describe the method for safeguarding confidentiality and/or measures for protecting anonymity. (Inform the Board where the data will be kept and plans for disposition at the completion of the study.)

8. If the study will involve an interview, describe where and in what context the interview will take place. (The approximate length of time required for the interview should be stated in the consent form.)

9. If the final survey instrument is not submitted with the IRB Form I (Attachment 3), the following information should be included in the abstract summary:

   a. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy;
   b. Examples of the type of specific questions to be asked in the sensitive areas; and
   c. Indicate when the questionnaire will be presented to the Board for review.

ATTACHMENT 5

COMPONENTS OF INFORMED CONSENT

1. Invitation to participate in study.

2. Explanation of purpose of study.

3. Explanation of study procedures (as they relate to subject).

4. Assurance that subject has the right to refuse to participate, and that refusal will not place subject in jeopardy.

5. Assurance that subject has the right to withdraw from participation and that withdrawal will not place the subject in jeopardy.

6. Description of potential risks, discomforts, inconveniences, or threats to dignity involved in study.

7. Description of potential benefits of participation in study.

8. Description of compensation to be expected, whether monetary or otherwise (if applicable).

9. Disclosure of available alternatives (if applicable).

10. Assurance of confidentiality or anonymity.

11. Statement regarding contact person and an offer to answer questions about the protocol.

12. Statement regarding IRB contact person to answer questions about rights as a research participant.

13. Concluding statement noting that subject indicates by signature (or, in certain studies, return of completed questionnaire) that he/she has read the information and has decided to participate.

14. Individual agency may require statement that agency will not provide compensation in case of injury resulting from participation.

16. Special restrictions apply to minors or individuals whose ability to give informed consent may be compromised. In these cases, if participant consents to participation, an "ability to consent" evaluation must be included in the consent procedures. If proxy, surrogate, parental or guardian consent is obtained, prospective participants should assent to participation whenever possible.